NDA 16-059/S-088
NDA 17-814/S-028
NDA 18-185/S-051
NDA 18-332/S-021

Merck Research Laboratories
Attention: Michelle W. Kloss, Ph.D.
Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. Kloss

Please refer to your supplemental new drug applications dated October 2, 1995, received October 3, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Indocin (indomethacin) Capsules (NDA 16-059);
Indocin (indomethacin) Suppositories (NDA 17-814);
Indocin (indomethacin) SR Capsules (NDA 18-185); and
Indocin (indomethacin) Oral Suspension (NDA 18-332).

We acknowledge receipt of your submissions dated October 2, 1995.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS AND HOW SUPPLIED sections of the label.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling [package insert submitted October 2, 1995]. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sharon Schmidt, M.S., Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonca Bull

10/31/01 09:06:35 AM